JUDGMENT OF THE COURT
27 October 1992 *

In Case C-191/90,

REFERENCE to the Court under Article 177 of the EEC Treaty by the Court of Appeal of England and Wales for a preliminary ruling in the proceedings pending before that court between

Generics (UK) Limited,

Harris Pharmaceuticals Limited,

and

Smith Kline and French Laboratories Limited,

on the interpretation of Articles 30 and 36 of the EEC Treaty and the Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic and the adjustments to the Treaties,

THE COURT,

composed of: O. Due, President, G. C. Rodriguez Iglesias, M. Zuleeg, J. L. Murray (Presidents of Chambers), G. F. Mancini, F. A. Schockweiler, J. C. Moitinho de Almeida, F. Grévisse and D. A. O. Edward, Judges,

Advocate General: W. Van Gerven,
Registrar: H. Von Holstein, Deputy Registrar,

* Language of the case: English.

after considering the written observations submitted on behalf of:

— the Government of the United Kingdom of Great Britain and Northern Ireland, represented initially by Rosemary M. Caudwell, of the Treasury Solicitor's Department, and subsequently by Sue Cochrane, of the Treasury Solicitor's Department, acting as Agent,

— the Kingdom of Spain, represented initially by Carlos Bastarreche Sagües, Director General for Community Legal and Institutional Coordination, and subsequently by Alberto Jose Navarro Gonzalez, Director General for Community Legal and Institutional Coordination, and by Antonio Hierro Hernandez-Mora, Abogado del Estado, acting as Agents,

— Harris Pharmaceuticals Limited, by Kenneth Parker and Henry Carr, Barristers,

— Smith Kline and French Laboratories Limited, by Robin Jacob QC, Guy Burkill, Barrister, and Sebastian Farr, Solicitor, of Simmons and Simmons,

— Generics (UK) Limited, by Stephen Kon, Solicitor of S. J. Berwin and Co, assisted by Sheila Radford, Solicitor of S. J. Berwin and Co,

— Commission of the European Communities, by Richard Wainwright, Legal Adviser, acting as Agent,

having regard to the Report for the Hearing,

after hearing the oral observations of Generics (UK) Ltd, the Kingdom of Spain, the United Kingdom, represented by Sue Cochrane, of the Treasury Solicitor's Department, acting as Agent, assisted by Eleanor Sharpston, Barrister, and the Commission of the European Communities at the hearing on 16 June 1992,

after hearing the Opinion of the Advocate General at the sitting on 8 July 1992,

gives the following

Judgment

1 By order of 13 February 1990, received at the Court on 19 June 1990, the Court of Appeal of England and Wales referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty several questions relating to the interpretation of Articles 30 and 36 of the Treaty and of the Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic and the adjustments to the Treaties, in order to allow it to assess the compatibility with Community law of certain practices followed by the competent national authorities for the purpose of settling the terms of licences of right in respect of patents.

2 Those questions were put in connection with proceedings between Smith Kline and French Laboratories Limited (hereinafter referred to as 'SKF'), the proprietor of two United Kingdom patents for the pharmaceutical product 'Cimetidine', on the one hand, and Generics UK Limited ('Generics') and Harris Pharmaceuticals Limited ('Harris'), on the other. The dispute concerns the importation of the product into the United Kingdom from non-member countries and from Spain and Portugal.

3 Pursuant to the Patents Act 1977 SKF's patents were endorsed 'licences of right' from 9 March 1988.

4 According to the national legislation applicable to patents bearing such an endorsement and in particular section 46 of the Patents Act, any person is entitled as of right to a licence under the patent on such terms as may be settled by agreement

with the proprietor of the patent or, in default of agreement, by the Comptroller General of Patents ('the Comptroller').

5 The House of Lords has held that the Comptroller may have regard, for the purpose of settling the terms of such licences, to sections 48(3) and 50(1) of the Patents Act, concerning compulsory licences. Those provisions allow the Comptroller to take into account, in the exercise of his powers, the fact that the patent is not being worked for the purpose of manufacturing the product in the United Kingdom.

6 It is common ground that the practice of the competent national authorities is, pursuant to those provisions, to authorize the licensee of right to import the patented product from non-member countries where the proprietor of the patent works the patent by importing the product into the United Kingdom from other Member States and, conversely, to deny the licensee the right to import the product from non-member countries where the proprietor of the patent manufactures the product within the United Kingdom.

7 Pursuant to the national law in force, Harris and Generics sought from SKF a licence of right permitting them *inter alia* to import Cimetidine. Since the parties could not reach agreement, the matter was referred to the Comptroller and subsequently to the Patents Court.

8 Taking into account the fact that SKF manufactured Cimetidine in the form of raw material in Ireland and made up the finished product in the United Kingdom, the Patents Court included in the conditions for the licences of right requested by Harris and Generics a term prohibiting them from importing Cimetidine, as a finished product, from non-member countries and from Spain and Portugal. Those two Member States were equated with non-member countries on the basis of the transitional provisions in Articles 47 and 209 of the Act of Accession concerning

certain patents. The Patents Court refused however to include such a clause in respect of the importation of Cimetidine in raw-material form.

9 Both SKF and Harris and Generics appealed to the Court of Appeal, which stayed the proceedings and referred the following questions to the Court for a preliminary ruling:

'1. Is it compatible with Articles 30 and 36 of the EEC Treaty for a competent authority charged with settling the terms of a licence under a patent compulsorily endorsed "licences of right" to rely upon the provisions of sub-sections 48(3)(a) and 50(1)(c) of the Patents Act 1977 in determining whether or not to include as a term of such a licence the right to import patented products from outside the EEC? Is it contrary to Articles 30 and 36 for it normally to apply sub-sections 48(3)(a) and 50(1)(c) as requiring it to refuse a licence to import from another country when the patentee works the patent by manufacture in the United Kingdom but to grant a licence to import from a third country where the patentee works the patent by importation of products manufactured in other Member States of the EEC?

2. (a) Is the answer to the previous question affected by the fact that sub-sections 48(3)(a) and 50(1)(c) of the Patents Act 1977 apply to the grant of compulsory patent licences and provide that a compulsory licence may be granted in respect of a patent if the same is not being worked in the United Kingdom?

(b) Is the answer to the previous question affected if, in exercising its discretion as to whether or not to permit importation from a third country, the competent authority places reliance upon sub-sections 48(3)(a) and 50(1)(c) of the Patents Act 1977 in ascertaining what factors are relevant to take into account?

3. Having regard to the provisions of the Treaties of Accession of Spain and Portugal to the EEC and the judgment of the Court of Justice in Case 434/85 (*Allen and Hanburys Limited* v *Generics (UK) Limited* [1988] ECR 1245) is it contrary to Articles 30 and 36 of the EEC Treaty for the competent authority in settling the terms of a licence of right in respect of a patent for a pharmaceutical product to include a term restricting importation of that product from Spain or Portugal?'

10 Reference is made to the Report for the Hearing for a fuller account of the facts of the case, the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

The first and second questions

11 The first two questions are designed essentially to establish whether the authorities of Member States which are competent to settle, in the absence of agreement, the terms of licences of right may, without contravening Articles 30 and 36 of the Treaty, rely on national legislation such as sections 48(3) and 50(1) of the Patents Act in order to refuse the licensee of right authorization to import the products covered by the patent from non-member countries where the proprietor of the patent manufactures the product within the national territory and in order to grant such authorization where the proprietor of the patent works his patent by importing the product from other Member States of the Community.

12 It should be noted first that the Court, in its judgment in Case C-30/90 *Commission* v *United Kingdom* [1992] ECR I-829, held that the abovementioned provisions of sections 48 and 50 of the Patents Act are contrary to Article 30 of the Treaty inasmuch as they treat a situation where demand for the patented product is satisfied on the domestic market by imports from Member States other than the

United Kingdom as being one in which a compulsory licence may be granted for insufficient exploitation of the patent.

13 However, in that judgment the Court did not consider the question raised here of whether, on the basis of those national provisions, the competent authorities may, for the purpose of refusing or granting the licensee of right the authorization to import the product from non-member countries, take into account the Member State in which the proprietor of the patent manufactures the product without infringing Community law.

14 The Commission and SKF argue that, where national authorities adopt a practice of settling the terms of licences of right concerning imports from non-member countries according to the place where the proprietor of the patent manufactures the product, that practice affects trade between Member States by virtue of its discriminatory nature and hence infringes the provisions of Articles 30 and 36 of the Treaty.

15 The United Kingdom Government maintained in its written observations that the provisions of the Treaty concerning the free movement of goods could not be relied upon in order to challenge a practice followed by national authorities with respect solely to imports from non-member countries. However, at the hearing the representative of the United Kingdom Government conceded that, in the light of the judgment in *Commission* v *United Kingdom*, which was delivered after the submission of the written observations, the practice was discriminatory and incompatible with Community law.

16 Harris and Generics, for their part, argue that authorizing the licensee to import a patented product from non-member countries does not affect intra-Community trade and cannot therefore be contrary to Articles 30 and 36 of the Treaty.

17 As the Court has already held in its judgment in Case 51/75 *EMI Records Ltd* v *CBS United Kingdom Ltd* [1976] ECR 811, Articles 30 and 36 of the Treaty apply only to restrictions on imports affecting trade between Member States. The authorities competent to settle the terms of licences of right may therefore grant or refuse the licensee authorization to import the patented product from a non-member country without infringing those provisions of the Treaty.

18 On the other hand, in exercising their powers with respect to imports from non-member countries, those authorities are not entitled to apply criteria which, by their discriminatory nature, affect trade between Member States in contravention of Articles 30 and 36 of the Treaty.

19 It follows from the practice of the national authorities to which the national court refers that the licensee may be authorized to import the patented product from non-member countries where the proprietor of the patent does not manufacture the product within the territory of the Member State in which the patent was granted but imports the product from other Member States. The proprietor of the patent may in such circumstances be exposed to competition from imports from non-member countries to which he is not exposed when he works the patent by manufacturing the product within the national territory.

20 Such a practice is discriminatory because it encourages proprietors of patents to manufacture patented products within the national territory rather than to import them from other Member States. It is therefore capable of hindering intra-Community trade directly or indirectly, actually or potentially, and hence constitutes a measure having equivalent effect to quantitative restrictions on imports within the meaning of Article 30 of the Treaty (judgment in Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5).

21 Under Article 36 of the Treaty prohibitions and restrictions on imports justified on grounds relating to the protection of industrial and commercial property are permitted by that article on the express condition that they shall not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

22 As the Court has consistently held, where Article 36 is relied upon to protect industrial and commercial property, it permits derogations from the fundamental principle of the free movement of goods within the common market only in so far as such derogations are justified for the purpose of safeguarding rights which constitute the specific subject-matter of such property (see in particular the judgment in Case C-10/89 *HAG* [1990] ECR 1-3711, paragraph 12).

23 In the case of patents, the specific subject-matter of the industrial property is, in particular, the exclusive right of the patent proprietor to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, and also the right to oppose infringements (see in particular the abovementioned judgment in *Commission* v *United Kingdom*, paragraph 21).

24 In the situation referred to by the national court, there is no reason relating to the specific subject-matter of the patent which is capable of justifying the different treatment accorded by the national authorities. The reason for the difference in treatment is not the specific requirements of industrial and commercial property but the desire to favour production within the territory of the Member State concerned in accordance with the provisions of the national legislation.

25 Such a consideration, the effect of which is to frustrate the objectives of the Community as laid down in particular in Article 2 and specified in Article 3 of the Treaty, cannot be accepted as justification for a restriction on trade between Member States (abovementioned judgment in *Commission* v *United Kingdom*, paragraph 30).

26 Harris and Generics argue that this discriminatory practice is necessary in order to avoid the adverse consequences for competition and for the consumer which would arise in the absence of common rules relating to patents. In order to illustrate their argument, they point out that in a case such as the present they would not be entitled to the issue of licences of right in Member States other than the United Kingdom where SKF is the patent proprietor. Unless they were authorized by the United Kingdom authorities to import Cimetidine from non-member countries, they would be obliged to manufacture the product solely within the United Kingdom in conditions which would not allow them to place on the market a product which was competitive by comparison with the product manufactured in Ireland, at a lower cost, by SKF.

27 That argument must be rejected on the ground that the adverse effects for the economy and for consumers arising from the disparity in the legislation of the Member States and from the absence of common rules applicable to patents cannot in any event justify discriminatory national practices contrary to Articles 30 and 36 of the Treaty.

28 For those reasons the reply to be given to the first two questions is that Articles 30 and 36 of the Treaty must be interpreted as precluding the authorities of Member States competent to settle, in the absence of agreement, the terms of licences of right from relying upon provisions of national legislation in order to refuse the licensee of right the authorization to import the patented product from non-member countries where the proprietor of the patent manufactures the product within the national territory, and in order to grant such authorization where the proprietor of the patent works his patent by importing the product from other Member States of the Community.

The third question

29 The national court's question seeks in substance to establish whether Articles 47 and 209 of the Act of Accession of Spain and Portugal must be interpreted as

allowing the authorities of Member States competent to settle, in the absence of agreement, the terms of licences of right to prohibit, in possible derogation from Articles 30 and 36 of the Treaty, the licensee from importing a patented pharmaceutical product from Spain and Portugal.

30 With effect from 1 January 1986 Articles 42 and 202 of the Act of Accession abolished, by implied reference to Articles 30 and 36 of the Treaty, quantitative restrictions on imports and exports and also any measures having equivalent effect existing between the Community and the two new Member States.

31 It follows that the principles laid down by the Court on the basis of Articles 30 and 36 of the Treaty are applicable to trade between the Community and the two new Member States. The Court has consistently held that the proprietor of an industrial or commercial property right protected by the legislation of a Member State cannot rely upon that legislation to prevent the importation of a product which has been lawfully marketed in another Member State by the proprietor himself or with his consent. The Court has inferred from that principle that an inventor, or someone deriving rights from him, cannot invoke the patent which he holds in one Member State to prevent the importation of a product freely marketed by him in another Member State where the product is not patentable (judgment in Case 187/80 *Merck* [1981] ECR 2063, paragraphs 12 and 13).

32 However, Articles 47 and 209 of the Act of Accession expressly derogate, within the limits laid down therein, from the abovementioned provisions of Articles 42 and 202 of that Act and the principles flowing therefrom.

33 According to those provisions, the holder (or his beneficiary) of a patent for a pharmaceutical product filed in a Member State at a time when a product patent

could not be obtained in Spain or Portugal for that product may rely upon the rights granted by the patent in order to prevent the import and marketing of that product in the existing Member State or States where that product enjoys patent protection, even if that product was put on the market in Spain or Portugal for the first time by him or with his consent. That right may be invoked until the end of the third year after Spain or Portugal has made those products patentable.

34 SKF argues that, in the absence of express provisions to the contrary, Articles 47 and 209 of the Act of Accession are applicable to imports of patented pharmaceutical products in respect of which a licence of right has been granted and hence may justify, by way of derogation from Articles 30 and 36 of the Treaty, the refusal to authorize the licensee to import the products in question from Spain and Portugal.

35 The Commission, the Spanish and United Kingdom Governments and Harris and Generics argue that patents endorsed 'licences of right' are 'weak' patents which are necessarily excluded from the scope of the derogating provisions of Articles 47 and 209 of the Act of Accession.

36 They base their view on the judgment in Case 434/85 *Allen and Hanburys* [1988] ECR 1245, according to which the proprietor of such a patent merely has the right to obtain a fair return from the licensee, and thus ascribe to that judgment a scope which it does not have.

37 In that judgment the Court considered whether the prohibition on the importation into the United Kingdom of a product protected by a patent endorsed 'licences of

right' was necessary in order to ensure that the proprietor of the patent had the same rights with respect to importers that he enjoyed with respect to producers manufacturing the product within the national territory and could therefore be justified under Article 36 of the Treaty. It was solely for the purposes of defining those rights that the Court stated that, according to the United Kingdom legislation as interpreted by the national court, the proprietor of a patent endorsed 'licenses of right' merely retained the right to obtain a fair return from the licensee (paragraph 13). The Court therefore did no more than take note of the United Kingdom legislation and did not establish a Community definition of a 'weak patent' from which it would follow that a patent endorsed 'licences of right' was necessarily excluded from the scope of Articles 47 and 209 of the Act of Accession.

38 In order to interpret those articles, it is necessary to have regard to the actual wording of the provisions, according to which the proprietor of the patent 'may rely upon the rights granted by that patent in order to prevent the import and marketing' of the product.

39 The first condition for the application of those provisions is that the patent should grant its holder the right to prevent imports. If, where such a right exists, Community law prevents it from being used in such a way as to affect intra-Community trade contrary to Articles 30 and 36 of the Treaty, it is national law which, in the present state of Community law and in the absence of approximation of national legislation, defines the extent of the protection conferred by a patent or in respect of each type of patent.

40 In order to verify whether that condition is fulfilled, it is therefore for the national court to consider whether the protection conferred by national law includes the right of the proprietor to prevent imports.

41 Such an interpretation is consistent with the purpose of Articles 47 and 209 of the Act of Accession, namely to derogate in a limited area from the Community rules governing the free movement of goods and not to create new rights exceeding the protection conferred on the patent by national law.

42 The second condition governing the prohibition on importing patented products from Spain and Portugal concerns the fact that the provisions of Articles 47 and 209 of the Act of Accession merely confer upon the proprietor of the patent the option of preventing such imports. Those derogating provisions are therefore inapplicable unless the proprietor of the patent demonstrates his intention to exercise that option. Contrary to the view expressed by the Spanish Government in its written observations, the effect of that condition is not to prohibit the authorities of the Member States from applying those provisions themselves. However, for the provisions to apply in such a case the proprietor of the patent must have demonstrated his intention to exercise the right conferred upon him by Articles 47 and 209.

43 Consequently, the reply to the third question must be that Articles 47 and 209 of the Act of Accession of Spain and Portugal must be interpreted to the effect that the authorities of the Member States competent to settle, in the absence of agreement, the terms of licences of a right may, on the basis of those provisions and in derogation from the principles laid down by Articles 30 and 36 of the Treaty, prohibit the licensee from importing from Spain and Portugal a patented pharmaceutical product if national law confers upon the proprietor of the patent the right to prevent imports and if the proprietor exercises the right conferred upon him by Articles 47 and 209.

Costs

44 The costs incurred by the United Kingdom and Spanish Governments and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by the Court of Appeal of England and Wales by order of 13 February 1990, hereby rules:

1. **Articles 30 and 36 of the Treaty must be interpreted as precluding the authorities of Member States competent to settle, in the absence of agreement, the terms of licences of right from relying upon provisions of national legislation in order to refuse the licensee of right authorization to import the patented product from non-member countries where the proprietor of the patent manufactures the product within the national territory and in order to grant such authorization where the proprietor of the patent works his patent by importing the product from other Member States of the Community.**

2. **Articles 47 and 209 of the Act concerning the conditions of the accession of the Kingdom of Spain and the Portuguese Republic and the adjustments to the Treaties must be interpreted to the effect that the authorities of the Member States competent to settle, in the absence of agreement, the conditions of licences of right may, on the basis of those provisions and in derogation from the principles laid down by Articles 30 and 36 of the Treaty, prohibit the licensee from importing from Spain and Portugal a patented pharmaceutical product if national law confers upon the proprietor of the patent the right to prevent imports and if the proprietor exercises the right conferred upon him by Articles 47 and 209.**

Due Rodríguez Iglesias Zuleeg Murray

Mancini Schockweiler Moitinho de Almeida Grévisse Edward

Delivered in open court in Luxembourg on 27 October 1992.

J.-G. Giraud — Registrar

O. Due — President